



# Insufficient FDA Resources: Levelling the Playing Field and Reducing Fraud by Altering Incentives

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**Insufficient FDA Resources:  
Leveling the Playing Field and Reducing Fraud by Altering Incentives**  
By Luke McFarland

INTRODUCTION

In 1940, the Food and Drug Administration first issued a labeling guideline stating that the term “fresh” should not be used to describe products which have been subjected to heat or chemical processing.<sup>1</sup> In 1964, the FDA issued a guideline stating that orange juice specifically should not be labeled “fresh” if the juice is processed into concentrate at any time before sale.<sup>2</sup> In 1980, the FDA reissued its 1940 guideline.<sup>3</sup> Still, orange juice manufacturers continued to use the word “fresh” to describe juices that were made from concentrate. Some contended that “fresh” was part of their trademark and thus not subject to the guidelines. Others thought that their product was “fresh” because it reached the shelf only a few days after the oranges were picked. The reasons given were not important: the FDA never enforced any of the guidelines.<sup>4</sup>

In the late 1980’s, Procter and Gamble noticed that the market share of its orange juice, “Citrus Hill Select”, had started slipping.<sup>5</sup> Feeling that their competitors were gaining an unfair advantage by calling their from-concentrate products “fresh”, Procter and Gamble contacted the FDA to inquire if such terminology was allowable. The FDA replied that the terminology was in violation of FDA guidelines, but that at the current time they did not plan on allocating resources to stop its use.<sup>6</sup>

In 1990, Procter and Gamble changed the name of its product from “Citrus Hill Select” to “Citrus Hill Fresh

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<sup>1</sup>David Kiley, *FDA Seizes Citrus Hill*, BRANDWEEK, April 29, 1991 at 6.

<sup>2</sup>Id.

<sup>3</sup>Id.

<sup>4</sup>Barbara McDonald, *P&G Swears Off the ‘F’ Word in Wake of FDA’s ‘Fresh’ Campaign*, BEVERAGE WORLD PERISCOPE EDITION, May 31, 1991 at 8.

<sup>5</sup>*Label Honesty, A Fresh Start*, THE ECONOMIST, May 4, 1991 at 28.

<sup>6</sup>Peter Barton Hutt, addressing students of Food and Drug Law class at Harvard Law School (January, 2001).

Choice.” They also added the phrase “[w]e pick our oranges at the peak of ripeness. Then we hurry to squeeze them before they lose their freshness.”<sup>7</sup> The FDA objected to the use of the word “fresh”, citing the aforementioned labeling guidelines. Procter and Gamble stated that they would remove the offending word if the FDA would impose similar restrictions upon its competitors.<sup>8</sup> The FDA countered that they did not have the resources to track down every violator and convince them to come into compliance – however they maintained that Procter and Gamble would have to remove the word.

Procter and Gamble negotiated with the FDA on this issue over the course of approximately twenty months.<sup>9</sup> Procter and Gamble argued that “fresh” was just part of their name, and showed surveys indicating that consumers were not fooled into thinking that the product was not from concentrate. In addition to the clear statements that their product was from concentrate that were already displayed, Procter and Gamble offered to move the term “fresh choice” to another side of the carton and to add the phrase “means fresh taste.” The FDA maintained its tough stance, claiming that such additions would merely repeat the libel.<sup>10</sup> Frustrated, Procter and Gamble walked out of negotiations on April 22<sup>nd</sup> 1991.<sup>11</sup>

Two days later, on April 24<sup>th</sup>, 1991, the FDA seized 24,000 cartons of Procter and Gamble’s “Citrus Hill Fresh Choice” orange juice from a Minnesota warehouse.<sup>12</sup> Lacking the resources to go after every violator of the policy and not wanting to show favoritism to the big companies, the FDA chose to hit a few of the biggest violators. Procter “just happened to be in the wrong place at the wrong time,” said Peter Barton Hutt, a former FDA chief counsel.<sup>13</sup> Agency officials acknowledge they were looking for a visible target to show they were serious about misleading labeling, and orange juice was a good one.<sup>14</sup> The bold move made

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<sup>7</sup>*Label Honesty* at 28.

<sup>8</sup>McDonald at 8 (“[C]ompany chairman and chief executive Edwin Artzt said, ‘We had previously told the FDA that, while we felt we had done nothing wrong, we intended to drop the word ‘fresh’ from our labeling, beginning in late May, given some assurance that this would be enforced on all brands.’”)

<sup>9</sup>*Id.*

<sup>10</sup>*Label Honesty* at 28.

<sup>11</sup>*Id.*

<sup>12</sup>Pat Lenius, *FDA Seizes Citrus Hill Over Fresh Claims*, *Supermarket News*, May 6, 1991, at 121.

<sup>13</sup>Zachary Schiller and John Carey, *Procter and Gamble: On a Short Leash*, *BUSINESS WEEK*, Vol. 3223, July 22, 1991 at 76.

<sup>14</sup>*Id.*

national headlines, and smaller companies soon got the message that the FDA would not permit the use of the word “fresh” in violation of labeling guidelines.

Unfortunately, this FDA victory came with a substantial cost. Procter and Gamble, who had initiated conversations with the FDA over the “fresh” language in the first place, was hit hard. While a number of producers (of juice and other products) were also in violation of the guidelines, only Procter and Gamble and Ragu Foods were hit with the seizure. As a result, Procter and Gamble alone suffered the direct economic losses from the seizure, but more importantly they suffered the bad publicity that followed. The FDA rarely seizes goods, and particularly when the victim is a large company, such action makes national news and is written about in major magazines for months to follow. Procter and Gamble’s Citrus Hill brand, already struggling to compete in the orange juice market, was damaged by the implication that its producer was misleading its customers as to the quality of the product.

Procter and Gamble may not seem like the most sympathetic victim. However, the problem extends far beyond a single multi-billion dollar company. First, the problem is widespread. The problem of insufficient FDA resources means that a number of rules and provisions that are on the books are simply not enforced. Participants in various industries who report non-compliance or seek to authorize certain statements with the FDA are often penalized for their actions by becoming the scapegoat for industry-wide change. The problem extends beyond mere labeling requirements to every area that the FDA regulates. Insufficient resources mean lax enforcement, which results in unequal enforcement. Because there are thousands of regulations on the books, but only a handful are vigorously enforced, industry never really knows how far it can go with its questionable claims or fraudulent behavior. Industry therefore will be willing to “test the waters” by placing claims on their product which explicitly violate FDA regulations, and waiting to see if the FDA will enforce them. Furthermore, the issue is not merely one of fairness within an industry – it reaches to the consumer level. The FDA’s course of action in cases like the 1991 orange juice seizure will deter companies

from bringing violations to the FDA’s attention, as such companies are not insulated from FDA enforcement actions (and in fact may be more likely to be targeted as the scapegoat). Because the FDA does not have the resources to adequately respond to every complaint by a producer or consumer, reporting violations becomes pointless.

In our capitalist society, companies either compete or die. In order to gain a competitive advantage over rivals, producers are constantly attempting to push the boundaries of law. They characterize their product as healthy even if it is not,<sup>15</sup> they sell products that do not work as advertised,<sup>16</sup> they use gimmicks and advertising to boost sales, they put tiny amounts of food in huge containers. The United States has established the FDA to monitor and prevent these sorts of behavior. Unfortunately, with inadequate funding and resources, the agency’s hands are tied – the FDA must choose its battles and as a result, many socially beneficial rules and provisions go unenforced or under-enforced.

This paper seeks to explore the problems illustrated by the Procter and Gamble orange juice example provided above; namely, the peculiar side effects of inadequate FDA funding upon competition and rule compliance. Part I of this paper will describe the problem in detail, exploring the FDA’s resources and responsibilities, their effects on competition and compliance, and the various externalities associated with this particular issue. Part II of this paper will discuss ways in which various industries have attempted to circumvent and supplement FDA regulation. One obvious but unlikely solution is to increase the resources and funding available to the FDA. Some companies and industries have lobbied congress for special laws or to force the FDA to regulate. Others have pursued false advertising claims under the Lanham Act, tort suits against individual violators (for fraud, fraudulent inducement, negligence, false advertising, and RICO violations), and suits against the FDA for failing to perform their duties. Many others have utilized

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<sup>15</sup>e.g., until FDA regulation, Crisco prominently displayed that its product was “cholesterol free”, despite the fact that it is 100% fat.

<sup>16</sup>e.g., the Fat-Be-Gone ring which taps into the “principles of acupuncture and acupressure,” to create the same effect as “jogging up to six miles a day,” all with no drugs, no starving, no sweating.” See Greg Winter, *Fraudulent Marketers Capitalize On Demand for Sweat-Free Diets*, N.Y. Times, Oct. 29, 2000, Sec. 1, Pg. 1.

self-regulatory instruments such as the National Advertising Division of the Better Business Bureau to enforce truthfulness in product claims. While these various mechanisms have helped to solve the problem of widespread disregard of FDA rules and to level the playing field, they each have serious drawbacks. Lobbying Congress is expensive, difficult, and uncertain. Protracted litigation suffers from the same drawbacks. Agencies such as the Better Business Bureau are willing to investigate complaints and violations, but have no binding authority. These mechanisms have their place in the field, but must be supplemented.

Part III of this paper proposes a way in which limited FDA resources could be used more efficiently to encourage industry to notify the agency of violations while simultaneously encouraging violators to cease their offending behavior before formal FDA action is taken towards them or an industry leading scapegoat. Currently, the FDA is willing to provide their opinion on the legality of any particular course of action. For example, if you want to know if your company can use the word “lite” to describe a beer that has 200 calories, you can ask the FDA. The real problem is enforcement: if they tell you that this violates FDA regulations, you may insist that your competitors with similar products also refrain from using the label. But with numerous more pressing and important issues to deal with and a limited staff and budget, the FDA cannot enforce every regulation directly.

My proposal seeks to alter the costs and benefits of FDA rule violation by increasing penalties when appropriate and making enforcement more likely, thus reducing the aggregate amount of rule violation and leveling the playing field. I argue that this goal can be accomplished without significant increases in FDA spending, and perhaps could even reduce spending and increase funding. Part III will describe my proposed solution in detail, outlining its predicted effects on FDA regulation, its advantages, and disadvantages.

## PART I. The Problem.

The problem which this paper proposes to alleviate is illustrated by the Procter and Gamble orange juice example described above. Essentially, insufficient FDA resources result in incomplete enforcement of FDA regulations. Those regulations that are of relatively less importance are sporadically enforced. This lax and scattered enforcement creates holes, which players in various industries attempt to exploit in order to gain a competitive advantage over their rivals. Some players in the industry may solicit the FDA's help to level the playing field by enforcing their guidelines. However, if the problem is not yet widespread it may not be a priority for the FDA and thus scarce resources will not be allocated to fix it. Seeing that the regulations will not be enforced, the rest of the industry often must similarly violate the regulations so as to prevent the rival from gaining a competitive advantage. Once an entire industry is violating the regulation, it often rises to a sufficient level to warrant FDA enforcement. Because the FDA lacks the resources needed to go after every violator, they usually choose one or two industry leaders and make an example out of them. The rest of the industry will generally fall in line after a move by the FDA.

As stated above, this frequently repeating scenario is problematic for several reasons. These will be described in detail in the following subsections. By gaining an intricate knowledge of the forces involved in the creation of this peculiar problem, we will be better able to develop and critique potential solutions.

a.

It is widely recognized that the FDA is inadequately funded. The FDA is charged with ensuring the accuracy and safety of approximately 25% of all consumer products in the market.<sup>17</sup> Their duties extend to cover

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<sup>17</sup>*Agricultural , Rural Development, and Related Agencies Appropriation Bill*, S. REP. NO. 101-84, (1989), reproduced in Peter Barton Hutt and Richard A. Merrill, *FOOD AND DRUG LAW: CASES AND MATERIAL*, 2<sup>nd</sup> Ed., (The Foundation Press, Inc. 1991) at 21-22.

human and animal food, human and animal drugs, medical devices, cosmetics, nutritional supplements, radiological products and use, and a variety of other areas. Yet in 1990, the FDA's budgetary allotments lag behind other agencies with far more circumscribed duties. For example, the USDA's Food Safety Inspection Service (FSIS), charged only with inspecting meat and poultry processing facilities, employed 7300 inspectors and had a \$417,000,000 budget in 1990. The FDA, which is responsible for the safety of all other foods, had only 800 inspectors and an operating budget of \$134,000,000.<sup>18</sup> And while the duties of the FDA have increased dramatically since its inception in both magnitude and scope, its funding has rarely kept pace. For example, from 1979 to 1989, 23 new laws were passed that expanded FDA authorities. However, in 1989 the FDA had 800 fewer employees than in 1979 with which to accomplish their important tasks.<sup>19</sup>

The problem of insufficient FDA resources is difficult to describe in quantitative terms simply because the dimensions of FDA regulation are so immense. The problem can be better understood by consulting experts in the field, and is aptly described by Peter Barton Hutt, former FDA Chief Counsel, in an article in the *Legal Times of Washington*.<sup>20</sup> Hutt notes that in the 70's, the FDA generally had the resources required to take regulatory action against flagrant or industry-wide violations. However, as the scope and quantity of the FDA's duties began grow faster than their resources, the agency was forced to "cut back drastically on its regulatory activity regarding economic violations of the [Food, Drug, and Cosmetics Act]."<sup>21</sup> "Industry requests that the FDA enforce the act's economic provisions have been met with a standard FDA response, both orally and in writing, that the agency's limited resources simply do not permit enforcement activities in this area."<sup>22</sup> Hutt goes on to note that the FDA has forthrightly stated that it "simply will not enforce certain

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<sup>18</sup>Chryssa V. Deliganis, *Death by Apple Juice: The Problem of Foodborne Illness, the Regulatory Response, and Further Suggestions for Reform*, 53 FOOD DRUG L.J. 681, 703 (1998).

<sup>19</sup>S. REP. NO. 101-84, (1989).

<sup>20</sup>Peter Barton Hutt, *FDA Reduces Economic Regulation of Food Industry*, LEGAL TIMES OF WASHINGTON, August 30, 1981, at 31, reproduced in Peter Barton Hutt and Richard A. Merrill, FOOD AND DRUG LAW: CASES AND MATERIAL, 2<sup>nd</sup> Ed., (The Foundation Press, Inc. 1991) at 1056-1057.

<sup>21</sup>Id.

<sup>22</sup>Id.



parts of the act. . . even flagrant and widespread violations have been included within this new policy.”<sup>23</sup> The limited resources of the FDA have forced them to prioritize the areas that it regulates. “Our high priorities are health hazards, filth, and nutrition. Our lowest priorities are food economics and food standards.”<sup>24</sup> Inadequate funding of the FDA is a persistent problem that does not seem likely to be remedied in the near future – falling taxes, balanced budgets, and tight governmental spending will all prevent the type of budget increase needed to make substantial improvements in FDA resources.

b.

Another problematic aspect evidenced by the orange juice example is competitive rule breaking. “[T]he FDA’s continuing failure to enforce the FDCA’s economic provisions invites serious problems both for consumers and for regulated industry. Such a policy encourages less responsible manufacturers to flaunt the law and can force even the most respectable members of the industry to cut corners in order to meet competition.”<sup>25</sup> Competitors should not feel obligated to violate FDA regulations just to keep pace with their rivals. Each player in an industry should be able to count on the FDA to prevent the acquisition of a competitive advantage but a less scrupulous member in the field. Furthermore, consumers should be insulated from the fraudulent and potentially dangerous effects of competition-driven rule violation.

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<sup>23</sup>Id.

<sup>24</sup>Agency response to National Milk Producers Federation opposition to its regulations regarding “imitation” labeling on cheeses with substitute dairy products. Id.

<sup>25</sup>Id.

A major factor in the problem as described is the role of publicity. This issue can be broken down into two parts. The first part deals with the role that publicity plays in the FDA's choice of "victims" for its limited enforcement mechanisms. More specifically, a major part of the problem is that it indeed makes a great deal of sense for the FDA to attack a market leader in order to make big headlines. Smaller players in the industry will get the news that the FDA is now enforcing a particular guideline and will quickly mend their ways. In this way, the FDA need only seek to enforce regulations against a single entity and thus saves the expense and time of seeking out and going after each entity individually. Major FDA enforcement actions may even induce compliance in other industries, as leaders in other areas take note of the FDA's strong actions in enforcing various guidelines. For example, the FDA action against Procter and Gamble in 1991 was seen by many as an attempt by Commissioner David Kessler to "draw a line in the sand" and "show that the FDA's bite [was] worse than its bark."<sup>26</sup>

Unfortunately, it is this same publicity that causes the most damage to the company singled out as the victim of FDA enforcement. Many commentators have argued that publicity should be used as the ultimate weapon of the FDA – many big companies might be willing to pay the small fines associated with many violations and continue the illegal conduct. The "dreaded publicity" is "the real punishment."<sup>27</sup> But while fear of bad publicity may be the main factor motivating compliance with FDA regulations, it seems fundamentally unfair that one or two companies should be singled out to receive the "dreaded" punishment. True, the persecuted company is certainly not innocent – but they are usually no more guilty than any other member of the industry. Perhaps in accordance with their limited resources, the FDA is not required to enforce regulations equally or across an entire industry.<sup>28</sup> Ideally, however, enforcement would occur across the board

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<sup>26</sup>See David Kiley, *FDA Seizes Citrus Hill*, BRANDWEEK, April 29, 1991 at 6.

<sup>27</sup>Arthur Kallet and F.J. Schlink, *100,000,000 Guinea Pigs* (1933), reproduced in Peter Barton Hutt and Richard A. Merrill, FOOD AND DRUG LAW: CASES AND MATERIAL, 2<sup>nd</sup> Ed., (The Foundation Press, Inc. 1991) at 1194.

<sup>28</sup>See generally Peter Barton Hutt and Richard A. Merrill, FOOD AND DRUG LAW: CASES AND MATERIAL, 2<sup>nd</sup> Ed., (The Foundation Press, Inc. 1991) at 1045 – 1055.

so as to avoid singling out a single company as a scapegoat.

## Part II. Industry Efforts to Obtain Enforcement: a Partial Solution

Confronted with the problem of under-enforcement and uneven playing fields, innovative industries and creative legal teams have attempted various methods to enforce FDA regulations. This section will detail many of those efforts, ultimately concluding that while they appropriately provide adequate remedy in some cases, they do not ultimately solve the problem at hand. Typically requiring the outlay of significant amounts of money and the assumption of great amounts of risk and uncertainty, these methods are no substitute for adequate FDA regulation.

a.

Occasionally, various parties have brought suit in an attempt to force the FDA to exercise its regulatory powers. The Supreme Court definitively answered the question of whether a court can review agency decisions not to enforce a particular regulation in *Heckler v. Chaney*.<sup>29</sup> In *Heckler*, several prison inmates petitioned the FDA, alleging that the use of certain drugs for lethal injection of death row inmates violated the FD&C Act. The FDA refused the request to exercise their regulatory authority. The inmates then filed suit alleging that the FDA's refusal was both reviewable and an abuse of discretion. The Court of Appeals for the District

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<sup>29</sup>470 U.S. 821.

of Colombia agreed, remanding the case “with directions that the agency be required to ‘fulfill its statutory function.’”<sup>30</sup>

The Supreme Court granted cert. Without tackling the “thorny issue” of FDA jurisdiction, the Court held that there was no judicial authority to review determinations by the FDA *not* to exercise its enforcement authority.<sup>31</sup> First, an agency decision not to enforce will usually involve complex factors which are “peculiarly within its expertise.”<sup>32</sup> The agency is in the best position to determine whether or not a violation has occurred, whether or not limited resources are best devoted to one violation or another, whether the agency is likely to succeed if it acts, and whether the enforcement action in question best fits the agencies overall policies. Furthermore, “when an agency refuses to act it generally does not exercise its *coercive* power over an individual’s liberty or property rights, and thus does not infringe upon areas that courts often are called upon to protect.”<sup>33</sup> For these reasons, an agency decision not to act is presumptively unreviewable. If the particular statute establishing the agency’s enforcement power makes clear the circumstances in which an agency is bound to take action, failure to do so under proper circumstances will be reviewable by the courts.<sup>34</sup> The Court here analyzes the FD&C Act and determines that its language is permissive – for example, “The secretary is *authorized* to conduct examinations and investigations,” and offending food, drugs, or cosmetics “shall be liable to be proceeded against.”<sup>35</sup> The Court notes that the rare parts of the statute which are phrased as mandatory, such as the section on criminal sanctions stating that violators of the act “shall be imprisoned. . . or fined,” cannot be logically interpreted to require such action in all circumstances.<sup>36</sup>

Thus, the Supreme Court has definitively answered in the negative the question of whether individuals or corporations may sue to force the FDA to utilize its regulatory powers. A limited exception has been carved

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<sup>30</sup>Id. at 823, *quoting Heckler v. Chaney*, 718 F.2d 1174, 1191 (1983).

<sup>31</sup>Id. at 828.

<sup>32</sup>Id. at 831.

<sup>33</sup>Id. at 832.

<sup>34</sup>Id. at 833.

<sup>35</sup>Id. at 835.

<sup>36</sup>Id.

out by a District Court in the Eastern District of New York – which has held that where FDA regulations themselves establish a required course of agency action, a suit can be maintained for failure to hold to that course of action.<sup>37</sup> Still, this potential solution to the problem at hand has been all but eliminated. The opposite holding by the Supreme Court would have been extremely problematic. Allowing private parties to require enforcement of FD&C Act provisions would stretch the FDA beyond the limitations of their budget and would be completely impracticable without increased resource availability.

Actions have also been brought against the United States for FDA failure to enforce, essentially alleging negligence in the performance of their duties. For example, claims have been brought when the FDA approved drugs that were later found to be dangerous,<sup>38</sup> wrongfully refused to approve a new drug,<sup>39</sup> or seized perishable goods that were not adulterated.<sup>40</sup> Courts have given the FDA wide latitude in their enforcement choices, refusing to find liability due to the large amount of discretion involved in making these difficult decisions.<sup>41</sup> As a result, suits against the government under these theories provide no solution to our dilemma.

b.

For several years, many legal scholars believed that a private right of action under the FD&C Act might be allowed.<sup>42</sup> For example, if the FDA chose not to enforce a particular regulation, an injured consumer or competitor could bring suit, and the issue could be adjudicated in court. With only a few limited exceptions

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<sup>37</sup> *Heterochemical Corp. v. FDA*, 644 F. Supp. 271 (E.D.N.Y. 1986).

<sup>38</sup> *Gray v. United States*, 445 F. Supp. 337 (S.D. Tex. 1978).

<sup>39</sup> *Hogan v. FDA*, 1965-1968 FDLI Jud. Rec. 376 (S.D. Cal. 1965).

<sup>40</sup> *Mizokami v. United States*, 414 F.2d 1375 (Cl. Ct. 1969).

<sup>41</sup> The Tort Claims Act prohibits such suits against the government for claims “based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty.” 28 U.S.C. 2680.

<sup>42</sup> See generally Cole & Shapiro, *Private Litigation Under the Federal Food, Drug, and Cosmetic Act: Should the Right to Sue be Implied?*, 30 FDC L.J. 576 (1975); Sales, *Does the FDC Act Create a Private Right of Action?*, 38 FDC L.J. 501 (1973).

that do not apply to the topic at hand, courts have held that the FD&C Act does not create or allow for a private right of action.

*Florida ex rel. Broward County v. Eli Lilly & Co.* is illustrative of this line of cases.<sup>43</sup> In this case, the State of Florida brought suit on its own behalf and on behalf of consumers and purchasers of certain drugs manufactured by the defendant. The complaint alleged that the defendants had falsely represented the effectiveness and side-effects of the drugs, which is actionable under provisions of the FD&C Act. The court dismissed the action, stating unequivocally that “[t]he Federal Food, Drug, and Cosmetic Act does not create a private right of action.” Section 307 of the Act states that all proceedings for the enforcement of the Act shall be brought by the United States, and the legislative history shows that early versions of the bill originally provided for a private right of action but that the clause was omitted after various attacks.<sup>44</sup> Various other District Courts have similarly held that there is no private right of action under the FD&C Act.<sup>45</sup>

In *Merrell Dow Pharmaceuticals, Inc. v. Thompson*,<sup>46</sup> the Supreme Court held 5-4 that an allegation of an FD&C Act violation as an element of a state cause of action could not be brought in a Federal Court. In so holding, both the majority and dissenting opinions assumed that the FD&C Act does not create a private right of action for individuals injured by conduct that violates the act’s provisions. Given the unified opinion of the courts who have weighed in on the subject, including Supreme Court dicta, it is safe to assume that private causes of action will not be allowed to proceed under the FD&C Act.

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<sup>43</sup>329 F. Supp. 364 (S.D. Fla. 1971).

<sup>44</sup>*Id.* at 365.

<sup>45</sup>*See* Peter Barton Hutt and Richard A. Merrill, *FOOD AND DRUG LAW: CASES AND MATERIAL*, 2<sup>nd</sup> Ed., (The Foundation Press, Inc. 1991) note 1 at 1218-1219 (collecting cases).

<sup>46</sup>478 U.S. 804 (1986).

One legal option that remains open to aggrieved consumers or competitors is a suit based on common law theories such as fraud, negligence, or breach of warranty. While the FD&C Act does not allow for a private remedy, a violation of the duties imposed by the Act may constitute per se fraud, negligence, etc. Just as many states regard violation of motor vehicle statutes as negligence per se, many states will regard violation of FDA regulations as per se unlawful. Using the orange juice example which began this paper, Procter and Gamble could have brought a state common law action against a particular competitor alleging that the labeling was per se fraudulent because it violated FDA regulations.

Other state laws may also provide for remedies. For example, state food and drug laws may allow an independent private cause of action, or there may be other specific state statutes that provide for remedies.<sup>47</sup> While a state-by-state survey is outside of the scope of this paper, it is important to note that these remedies are available, although inconsistent.

Reliance on common law remedies is problematic, and does not adequately solve this problem presented in this paper. First and foremost, widespread enforcement against a number of violators is difficult and expensive because individual actions may have to be filed in each state in which a violator operates because these claims are based on state law. Depending upon the state, a variety of different procedural and legal requirements may exist. Furthermore, litigation is costly, slow, and risky. For these reasons, parties will resort to litigation at a sub-optimal level – consumers will suffer and competitive irregularities will persist.

d.

One of the most widely used methods of stopping competitors from making fraudulent or misleading claims is

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<sup>47</sup>See, e.g. *Committee on Children's Television, Inc. v. General Foods Corp.*, 673 P.2d 660 (Cal. 1983); *National Women's Health Network, Inc. v. A.H. Robbins Co., Inc.*, 545 F.Supp. 1177 (D.Mass. 1982).

a suit under the Lanham Act.<sup>48</sup> The Lanham Act provides that any person who is damaged or is likely to be damaged by false or misleading representations may bring a civil action against such representations about their products.<sup>49</sup> Potential remedies for violations include injunctive relief, damages, recovery of profits, and destruction of infringing materials.<sup>50</sup>

The intersection between FDA regulation and Lanham Act liability can be dispositive in some cases. For example, courts have held that a drug claim not approved by FDA – even if supported by scientific studies and journal arguments – is false under the Act and hence actionable. In *Zeneca Inc. v. Eli Lilly & Co.*,<sup>51</sup> the district court under the Lanham Act entered an injunction barring Eli Lilly from claiming that its drug Evista reduces the risk of breast cancer because evidence supporting this claim is inconclusive and thus FDA has not approved Evista for that use. This type of *per se* Lanham Act violation would aid plaintiffs in some situations, but would not apply in the paradigmatic case, where a statement violates an unenforced FDA regulation.

The Lanham Act provides an excellent way for companies to force competitors to refrain from using false and misleading advertising and branding. Still, it has deficiencies and does not adequately solve the problem of lax FDA enforcement. First, consumers have no right of action under the Lanham Act, only competitors.<sup>52</sup>

While it is unclear how significant this factor is (that is, how often consumers will be damaged and willing

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<sup>48</sup>60 Stat. 427 (1946). As amended by 102 Stat. 3935, 3946 (1988), § 43(a) of the Lanham Act reads:

Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which-

(1) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin of sponsorship, or approval of his or her goods, services, or commercial activities by another person, or

(2) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,

shall be liable in a civil action by any person who believes that he or she is likely to be damaged by such act.

<sup>49</sup>*Id.*

<sup>50</sup>For a myriad of Lanham Act cases, see Peter Barton Hutt and Richard A. Merrill, FOOD AND DRUG LAW: CASES AND MATERIAL, 2<sup>nd</sup> Ed., (The Foundation Press, Inc. 1991) note 2 at 1233 (collecting cases).

<sup>51</sup>No. 99 CIV. 1452(JGK), 1999 WL 509471 (S.D.N.Y. July 19, 1999).

<sup>52</sup>See *Florida ex rel. Broward County v. Eli Lilly*, supra note 43 (dismissing Lanham Act claim stating “the commentators agree that members of the general public, as consumers, have no right of action under the Lanham Act”).



to sue without a corresponding damage to a competitor who is willing to sue), this wrinkle does open up the possibility of unrecompensed damage to consumers. The risk, delay, and expense of litigation are significant additional problems that make suits under the Lanham Act imperfect substitutes for prompt FDA action.<sup>53</sup> Moreover, a successful Lanham Act suit requires various additional layers of proof. For example, a plaintiff carries the burden of proving that the statements are false or misleading (an often difficult task), and must prove that they were damaged by the false or misleading statement. Thus, it is more difficult to win a Lanham Act suit than it is for the FDA to establish that a violation of their regulations has occurred.

e.

Industry has attempted to utilize Congress to put pressure on the FDA to enforce certain regulations in two different ways, with varying degrees of success. The first method that has been employed is to pressure individual congressmen to contact the FDA. For example, a large food manufacturer from a particular state would convince one of its representatives to lobby the FDA for some particular enforcement action. This method of pressuring the FDA has been mostly unsuccessful. “The FDA has responded to congressional letters on behalf of constituents in much the same way that it has responded to the food industry in general.”<sup>54</sup>

Industry has had more success forcing FDA action by going through the congressional appropriations committee. Another orange juice example demonstrates that industry can obtain favorable results by threatening the already strained budget of the agency. In the Senate report on the FDA’s fiscal 1981 appropriations,

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<sup>53</sup>In some extreme cases, attorney’s fees may be awarded to prevailing plaintiffs. This may reduce the deterrent effect that litigation costs have on suits under the Lanham Act.

<sup>54</sup>Peter Barton Hutt, *FDA Reduces Economic Regulation of Food Industry*, LEGAL TIMES OF WASHINGTON, August 30, 1981, at 31, reproduced in Peter Barton Hutt and Richard A. Merrill, FOOD AND DRUG LAW: CASES AND MATERIAL, 2<sup>nd</sup> Ed., (The Foundation Press, Inc. 1991) at 1056-1057.

the appropriations committee expressed concern that adulterated frozen orange juice concentrate and adulterated orange juice from concentrate were increasingly prevalent in the marketplace.<sup>55</sup> The committee noted that this trend was a threat to consumers and was “work[ing] an economic hardship on growers and processors who produce a pure product.”<sup>56</sup> “The committee stated its belief that the FDA ‘should pursue a rigorous enforcement policy with respect to any violations of the Federal standards of identity for orange juice,’ and directed the agency to submit a report of its plan for enforcement within three months of the appropriations bill’s enactment.”<sup>57</sup> The FDA quickly snapped to attention, bringing formal seizure actions against 800 55-gallon drums of adulterated orange juice.<sup>58</sup>

Thus, congressional lobbying by industry can be an effective way to force the FDA to enforce certain regulations, leveling the playing field and reducing harm to the consumer. However, this method has serious drawbacks. First, only a few large companies will be able to spend the money and exert the kind of influence needed to convince key members of Congress to force the FDA’s hand. If congressional pressure is the only way to obtain enforcement, most companies will be left without a remedy. Furthermore, the process is slow and cumbersome. Even for corporations that wield great influence in Washington, relief will must come through a tedious and inefficient process. Additionally, the outcome is uncertain given the number of variables involved – whether members of Congress support the action, whether the provision will pass, whether the FDA listen to Congress, whether the enforcement chosen by the FDA will comport with that sought by the industry.

The inefficiency and inequality of the congressional route make it a poor substitute for adequate FDA enforcement. Congress is simply not in an effective position to micro-manage the affairs of the FDA. While

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<sup>55</sup>S. REP. NO. 96-1030, at 100 (1980).

<sup>56</sup>*Id.*

<sup>57</sup>Peter Barton Hutt, *FDA Reduces Economic Regulation of Food Industry*, LEGAL TIMES OF WASHINGTON, August 30, 1981, at 31, reproduced in Peter Barton Hutt and Richard A. Merrill, FOOD AND DRUG LAW: CASES AND MATERIAL, 2<sup>nd</sup> Ed., (The Foundation Press, Inc. 1991) at 1056-1057; quoting S. REP. NO. 96-1030, at 100 (1980).

<sup>58</sup>*Id.*

this route certainly is an effective way for some large companies to exercise their political clout and obtain some measure of competitive “equality” in their industry, it must certainly be augmented by other methods.

f.

Perhaps the most interesting industry development helping to alleviate the problem of FDA under-funding and under-enforcement is the Better Business Bureau (BBB). The BBB was founded in 1912, and today is supported by 250,000 local business members nationwide.<sup>59</sup> The BBB is “[d]edicated to fostering fair and honest relationships between businesses and consumers, instilling consumer confidence and contributing to an ethical business environment.”<sup>60</sup> Particularly relevant to the topic at hand is the National Advertising Division of the BBB, created in 1971. The National Advertising Division investigates complaints about misleading advertising claims and determines whether such claims have been substantiated.<sup>61</sup> The Division is composed of advertising experts, and often examines ad copy, lab tests, technical reports, and consumer surveys in deciding whether an advertisement is truthful and fair.<sup>62</sup> “The truth and fairness of an advertising claim can be challenged for a variety of reasons. For example, a claim may be blatantly false; a fact may be presented in a misleading way; disclaimers may be inadequate... the veracity of a claim can depend on the many shades of meaning that go with a certain phrase or word.”<sup>63</sup>

The decisions of the National Advertising Division, which are accompanied by specific recommendations for changes, are almost always adhered to by member companies. Companies who do not comply with Division

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<sup>59</sup>*About the Council of Better Business Bureaus*, BBB Official Website (visited 04/10/01) <<http://www.bbb.org/about/aboutCouncil.asp>>.

<sup>60</sup>*Id.*

<sup>61</sup>*Id.* Decisions may be reviewed by the National Advertising Review Board.

<sup>62</sup>Anthony Giorgianni, *Advertising: An Arm of the Council of Better Business Bureaus Challenges the Commercial Claims that Consumers or Competitors Don't Buy*, LOS ANGELES TIMES, Jan. 7, 1997 at E5.

<sup>63</sup>*Id.*

decisions lose their membership in the bureau, and lose the privileges associated with membership (including significant amounts of good publicity, legitimization, listing in BBB rosters, and consumer trust).<sup>64</sup> Furthermore, the BBB will report companies who do not comply with National Advertising Division recommendations to the Federal Trade Commission or the FDA.<sup>65</sup> The newspapers are replete with stories of large companies agreeing to change their ways after the National Advertising Division agreed with competitors that their advertisements were false, misleading, confusing, or fraudulent.<sup>66</sup>

This route presents perhaps the best current alternative to strict FDA enforcement provisions, and best makes an end-run around the problem of insufficient FDA resources. This method does have some shortcomings. First, not all companies are members of the BBB, which means that its enforcement mechanisms do not apply. Second, the BBB's enforcement mechanisms are limited. BBB membership is still a highly coveted status, but its denial is certainly not the end of the world for the less reputable companies who are employing these questionable practices. Third, a successful action with the BBB still involves substantial expenditure by the prosecuting company, although much less than with more traditional litigation attacks. A prosecuting company or consumer group must still prove that the advertisements or claims made by the alleged violator are false or misleading. This often involves the preparation of substantial studies, reports, and surveys, and a more difficult standard of proof than with the FDA.

g.

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<sup>64</sup>Membership in the BBB carries over a 98% favorable name recognition according to a Gallup poll, and 74% of consumers prefer doing business with a BBB member according to a Roper survey. See *Benefits of BBB Affiliation*, BBB Official Website (visited 04/10/01) < <http://www.bbb.org/bndsubpgs/bbbaffil.asp>>.

<sup>65</sup>See Giorgianni.

<sup>66</sup>See Greg Winter, *Fraudulent Marketers Capitalize On Demand for Sweat-Free Diets*, N.Y. Times, Oct. 29, 2000, Sec. 1, Pg. 1; Associated Press, *Procter agrees to change Pampers ad claims*, CHICAGO TRIBUNE, Dec. 30, 1992 at Business 4 (reporting that Procter and Gamble had agreed to change slogans that disposable diapers were healthier than cloth after BBB decision); Bloomberg Business News, *Procter & Gamble agrees to alter Aleve ads*, THE ATLANTA JOURNAL AND CONSTITUTION, November 12, 1994 at C12 (reporting that Procter and Gamble agreed to change Alleve ads after BBB finding that they misstated the qualities of competing painkillers); Anthony Giorgianni, *Advertising: An Arm of the Council of Better Business Bureaus Challenges the Commercial Claims that Consumers or Competitors Don't Buy*, LOS ANGELES TIMES, Jan. 7, 1997 at E5.

The various methods and strategies aimed at leveling the playing field and overcoming the problems caused by insufficient FDA resources have their place in our current scheme. They provide alternatives to total regulation by a single entity, and provide for flexibility, checks and balances, and self-regulation. Still, these alternatives do not provide an adequate solution to the problem at hand, either individually or in conjunction with one another. To one degree or another, each one of them involves added risk, expense, delay, uncertainty, ineffectiveness, or difficulty which make them sub-optimal.

### Part III. Increasing Compliance Without Increasing Resources: A Potential Solution

#### a. Introduction

In studying both the problem at hand and the inadequate solutions to it, a number of factors have emerged that present themselves as prerequisites for a good solution. Any potential solution will have to fit within these prerequisites if it hopes to improve upon the status quo. First, a solution should come from within the FDA. The FDA is in the best position to perform enforcement – they have the knowledge, experience, and power to do so effectively. Solutions which attempt to circumvent the FDA have the inherent problems of expense, risk, and illegitimacy. The FDA is able to regulate entire industries and among several industries simultaneously. Second, a solution must be resource-efficient in two ways. A good solution should minimize the resources required to undertake it. This is one main reason that the FDA should be involved in any good solution – their power makes them the most efficient enforcer. Also, in order to be feasible a solution must

operate within the reality of finite and extremely limited FDA funding. Third, a solution must discourage the competitive rule-breaking cycle that has emerged in many industries while encouraging rule obeying and violation reporting. Finally, a good solution should be driven by those aggrieved. In most cases, industries will be economically harmed by unfair competitive practices and will be willing to press for enforcement against violators. In some cases, consumers or groups of consumers will initiate proceedings. A good solution should accommodate both groups.

#### b. The Basic Theory Behind the Solution

As we know, the main problem is one of enforcement. Inadequate funding and prioritized enforcement lead to predictable holes in FDA attention and coverage. Less scrupulous players in competitive fields will exploit those holes by violating FDA regulations, say by making fraudulent or untested statements, not listing certain ingredients, violating safety standards, etc. These violations give a company a competitive advantage over other members of an industry, either by reducing their costs of production, by increasing the number of people who buy their product, or by allowing them to inflate their price. Faced with this situation, a company must either follow suit and adopt similar rule-breaking behavior, or somehow get the violator to cease its illegal actions. When these companies approach the FDA, the agency charged with enforcing these rules, they are told that insufficient resources prevent them from taking action. The rest of an industry, left with only expensive, risky, and relatively less powerful remedies, often sinks to the level of the violator, increasing fraud and deception to consumers.

The problem is not in getting the FDA to say what is or is not in violation of their regulations. The problem is getting them to devote the resources to locating violators, pressing charges, having hearings, negotiating, and occasionally litigating disputes. Even if the FDA is willing to take initial steps towards enforcing a

regulation, they may not be able to press the matter in the face of industry resistance.<sup>67</sup> How can we decrease the number of violations without increasing FDA resources?

Basic deterrence theory provides some answers. Essentially, when contemplating an illegal act, an entity does a simple analysis. They compare the benefits gained from the act versus the costs, which are discounted by the chances of getting caught. If you want to deter more criminal acts, you must either increase the severity of the punishment, or make the transgressor realize that the chances of getting caught are greater, or both.<sup>68</sup> The benefits of violating minor FDA regulations can be immense, including increased sales, profits, and market share. The chances of being caught are relatively small given the FDA's limited resources, and even if the violator is caught, the penalties for minor infractions are usually fairly light. In many situations, then, this simple cost-benefit analysis leads companies to violate FDA regulations that are not heavily enforced, and to err on the side of profitability rather than compliance.

In addition to bolstering FDA resources so that they can go after more violators, I propose that the incentives should be changed to stop violations before they become severe. I believe that there is room to alter the costs and benefits of rule breaking in order to deter more violations, and to convince violators to stop their illicit actions before the FDA is required to bring their resources to bear upon them.

### c. A Possible Solution

This proposed solution is rough – it is not intended to be a blueprint for reform, but rather a cluster of ideas designed to stimulate reform discussions and idea exchange. The specific details included herein are provided to give substance to my proposal, and are not presented as some ideal or “correct” method of implementing

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<sup>67</sup>See David Kiley, *FDA Seizes Citrus Hill*, BRANDWEEK, April 29, 1991 at 6 (describing that it was reasonable for P&G to stop negotiating with the FDA because it was unlikely that they would take further steps to enforce the regulation).

<sup>68</sup>See generally Johannes Adenas, *General Prevention – Illusion or Reality?*, 43 J. Crim. L., Criminology and Police Science 176, 179-180; Sanford Kadish and Stephen Schulhofer, *Criminal Law and It's Processes*, 6<sup>th</sup> ed. (Aspen Publishers, Inc., 1995), 115-119.

these ideas. The backbone of this proposal is the notion that by increasing the penalties for willful violation of FDA regulations, companies can be convinced to mend their ways.

At the request of an individual or company, the FDA could issue a preliminary opinion letter on the legality or illegality of a particular claim or label. This letter would be sent to all companies or producers specified by the party making the request. If the FDA's preliminary opinion is that the practice is illegal, each company on notice (the requestor and each company specified by the requestor) must cease the practice within a set time period, perhaps 60 days. This would allow all competing companies a reasonable amount of time to exhaust warehoused products, and would force them to compete under the same set of rules. If they do not comply with the opinion letter, the FDA does not immediately prosecute them. Rather, they are deemed "willful violators" and are subject to multiplied penalties and intensified criminal liability if and when the FDA chooses to crack down. If the FDA opinion letter states that the practice is legal, on the other hand, the FDA is limited in its choice of remedies should they later decide to regulate the conduct. For example, fines are reduced, and seizure and criminal penalties are not available.

This policy essentially increases the potential costs of rule violation. If the FDA acts against a violator without any prior action, the violator receives a slap on the wrist. If the FDA acts against a violator after warning them that their conduct violated a particular provision, they receive some greater punishment – criminal liability, multiple damages, costs, etc. Fear of these repercussions will make more violators cease their illicit activity after only a small resource allocation (composition of a warning letter) is made.

Deterrence theory also tells us that increasing penalties without increasing the likelihood of enforcement (the chances of being caught) has only insignificant results.<sup>69</sup> The doctrine also teaches that to increase deterrence, one need not actually increase the chances of catching the illegal activity, but must merely make potential transgressors feel that the chances are increased.<sup>70</sup> For example, placing an empty police car on a

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<sup>69</sup>See Johannes Andenaes, *The General Preventative Effects of Punishment*, 114 U. Pa L. Rev. 949, 961-962 (1960).

<sup>70</sup>Sanford Kadish and Stephen Schulhofer, *Criminal Law and It's Processes*, 6<sup>th</sup> ed. (Aspen Publishers, Inc., 1995), 117.



highway will reduce speeding, even though the presence of the car does nothing to increase the chances of catching speeders. With these principles in mind, as well as the limited resources available to the FDA, we must design a method of increasing enforcement or the perceived likelihood of enforcement to properly deter FDA violations.

I propose a system of complainant-paid fees to offset the costs of enforcement. If the FDA determines that they do not have sufficient resources to pursue a certain violation, a company, consumer, or group thereof should be able to provide the funding needed to prompt FDA action. The amount of litigation in the area clearly evidences that competitors and consumers groups are willing to spend money to obtain remedies. I submit that in most cases, it would be more efficient to simply provide the resources to the FDA and have them enforce the regulations, rather than to engage in protracted litigation. The implementation of user fees associated with review of new drugs greatly increased the speed and effectiveness of FDA action in that area. However, establishing this system will be tricky. Because user-fees would presumably only kick in once the FDA has decided that they do not have the resources to attack a certain violation, there is a risk that the FDA would be less willing to take on certain violations (because industry might pay for them if the FDA does not). The system should contain some penalty-driven funding on the back end, as well. Increasing penalties for willful violation could provide much of the additional funding needed to enforce the provisions. These methods would make enforcement of every violation economically feasible. Once those in the industry realize this, violations will become much more infrequent.

d.

This solution is not perfect. However, it appears that such a policy shift would substantially reduce the

negative effects currently caused by the lack of adequate FDA resources.

This policy keeps enforcement of FDA guidelines in the hands of those best equipped to assess violations and monitor compliance. Despite being under-funded, the FDA contains a huge body of expertise in food, drug, and cosmetic regulation. Indeed, their expertise is one reason why courts provide such a poor alternative to FDA enforcement – courts feel that it is not their position to second-guess the FDA. Keeping enforcement of these regulations within the entity that has been doing so since 1862 is advantageous.

This policy can work within existing budgetary constraints. Because substantial increases in funding are unlikely given the current political and budgetary climate and the history of FDA funding, a solution will have to be self-funding or extremely efficient. This solution is both. Increasing the severity of penalties will reduce the number of violations with no increase in the expenditure of resources. Allowing for the complainants to fund FDA investigation provides one source of funding for FDA enforcement, and the increases penalties may provide another. Both competitors and consumer groups would be able to lodge complaints, so that consumers can gain protection even if no one in the industry is willing to take the initiative. Furthermore, complaining by members of industry will not be deterred as by uncertainty as it sometimes is under the current regime.

This solution breaks the cycle of competitive rule-breaking. By increasing the costs of rule breaking, one makes it less profitable to acquire a competitive advantage via these improper means. By increasing the frequency of enforcement, companies will realize that ultimately any attempt to circumvent FDA regulations will be met with punitive measures. Once the honest members of an industry have a weapon with which to decimate these methods of gaining competitive advantages, they have no need to “sink to the level” of their less-honest counterparts. The playing field will be level.

While no solution is perfect, I hope that at the very least this paper has demonstrated that there are solutions to the problem of inadequate FDA resources. As funding for various important agencies shrinks relative to

their duties, innovation will be required to stretch what few resources there are as far as possible. The recommendations of this paper, if implemented properly, would significantly reduce the problems associated with incomplete FDA enforcement of its regulations.